

A I D S TREATMENT N E W S

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Contents

Modern HIV May Be Slightly Less Virulent, Laboratory Study Suggests..... 2

We use this well-publicized research finding as a starting point for discussion of different kinds of immune-based therapy.

Major U.S. Treatment-Access Problems Likely: Inadequate Political Response..... 3

2006 could be the worst year for U.S. access to HIV medical care since the development of lifesaving drugs. Our community needs to respond more effectively to this threat.

U.S. Treatment Guidelines: New Version, October 2005..... 4

The new edition has a small number of revisions.

New California Law: Insurers Cannot Deny Organ Transplants Solely Because of HIV..... 5

California has become the first state to decide that a health insurer cannot refuse to pay for a liver or other organ transplant solely because the patient has HIV.

One-Day HIV Treatment Meeting Near Boston, November 11..... 5

This meeting on new drugs, treatment strategies, and clinical trials will include talks by leading HIV physicians and researchers.

HIV Treatment in Resource-Limited Settings: Call for Information

AIDS Treatment News

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Statement of Purpose:

AIDS Treatment News reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations that work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

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To protect your privacy, we mail first class without mentioning AIDS on the envelope, and we keep our subscriber list

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AIDS Treatment News needs fact sheets for people with HIV in resource-limited settings, such as developing countries, where many drugs and tests commonly used in rich countries are not available. Despite vast geographical and political differences in treatment and access, some critically important background and suggestions can be provided to people directly, or for local experts and organizations to change as they wish. We are asking readers for advice on what has proved useful.

Got Medicare? What People Living with HIV Need to Know about the New Medicare Drug Benefit - "Part D" - Starting January 1st, 2006.....

Here is practical background on the new drug benefit, for persons on Medicare or eligible for it -- including details on who can qualify for the major low-income help in paying the fees.

Modern HIV May Be Slightly Less Virulent, Laboratory Study Suggests

by John S. James

A laboratory study comparing recent (2002-2003) vs. early (1986-1989) untreated HIV found that the recent virus reproduced somewhat less well, and appeared more sensitive to two antiretrovirals tested (3TC and TAK-779, a CCR5 antagonist no longer being developed as a drug). The authors suggested that "this 'attenuation' could be the consequence of serial bottlenecks during transmission and result in adaptation of HIV-1 to the human host." [1]

Comment

It is common for infectious diseases to become less severe after they have been in a population for a long time. One mechanism is that bacteria or viruses that kill people or animals too quickly have less time to spread, so greater virulence is a selective disadvantage. At the same time, the individuals more resistant to the disease are more likely to survive and reproduce. The new study [1] shows the first evidence that such attenuation of HIV (with the virus becoming less able to reproduce, and also less able to be transmitted) appears to have occurred.

The "bottlenecks" quoted above refer to the fact that HIV loses its genetic diversity when transmitted from person to person -- perhaps because only one virus or very few succeed in getting established in the newly infected person. Unfortunately genetic diversity then develops again, separately within each infected person, since HIV makes many mistakes in replication. This diversity is important in disease progression, as viruses can become less susceptible to control by parts of the immune system, much as they become resistant to drugs. The authors note that the transmission bottlenecks could result in overall reduction in viral fitness if more fitness is lost during each transmission than is gained as viral diversity develops again in the person infected [1] -- one possible mechanism for attenuation of HIV over time.

Other evidence suggests that when an animal population has long been infected by a retrovirus, the virus may be present with a high viral load, but the animal does not get sick -- while the same virus kills animals in other species where it is not native. [2] This seems to be how populations adapt to retroviruses (there are no human examples, as HIV was the first retrovirus found to infect humans). Of course no one wants to wait centuries for the HIV epidemic to control itself this way.

This animal observation supports the

belief that there could be two very different kinds of immune-based treatment -- helping the immune system suppress HIV and reduce viral load (much like antiretroviral drugs do), vs. preventing human responses to the virus that cause the symptomatic illness (this kind of treatment might not suppress viral load, and might even allow it to increase). There has long been some interest in "immune suppressive therapy," reducing immune responses to HIV infection that may do more harm than good in some patients.

The problem today is that little research has been done on immune-based treatment of any sort. We do not have a good understanding of what immune responses are needed to control HIV -- and while a handful of people have used immune-suppressive drugs like prednisone to treat HIV infection, these drugs were not developed or formally tested for that purpose, and little is known about whether, when, or how to do this safely. (Note: immune-based therapy was not discussed in [1].)

The immune system includes many different mechanisms; it should not be thought of as just more or less (as the phrase "boosting" the immune system wrongly implies). The practical importance of getting this picture right is that immune-based therapy that acts against HIV is not the opposite of immune-suppressive therapy. In the future, both kinds might be used -- even together in the same patient at the same time.

References

1. Arien KK, Troyer RM, Gali Y, Colebunders RL, Arts EJ, and Vanham G. Replicative fitness of historical and recent HIV-1 isolates suggests HIV-1 attenuation over time. *AIDS*. October 14, 2005; volume 19, number 15, pages 1555-1564.

[2] Rey-Cuille MA, Berthier JL, Bornsel-Demontoy MC, Chaduc Y, Montagnier L, Hovanessian AG, and others. Simian immunodeficiency virus replicates to high levels in sooty mangabeys without

inducing diseases. *Journal of Virology*. 1998; volume 72, pages 3872-3886.

Major U.S. Treatment- Access Problems Likely: Inadequate Political Response

Comment by John S. James

Medicaid cuts and other problems could make 2006 the worst year for U.S. treatment access since lifesaving drug combinations became available, according to experts quoted in an October 2005 article in *HIV Plus* magazine, available online. [1] Earlier in 2005 Congress agreed to cut \$10 billion from Medicaid over five years. And now Republicans are trying to make additional huge cuts in non-military Federal spending to balance the cost of rebuilding most of New Orleans after hurricane Katrina, when failure to maintain the levees led to flooding of 80% of the city.

The destruction from the storms is also causing huge medical problems as many people from the area cannot obtain and pay for treatment after their jobs, homes, and doctors' offices were destroyed. An estimated 21,000 people with HIV lived in the affected area. Leaders of both political parties in the Senate are trying to pass legislation to let people who lived there get Medicaid if they are poor enough to qualify, even if they are not aged, disabled, or in some other category. But a few conservatives, encouraged by the Bush administration, have refused to let the Senate vote on this measure. The more conservative House would probably block it as well. The objection is to the cost, about \$9 billion, and the precedent of expanding Medicaid. An October 5, 2005 action alert from the Campaign to End AIDS is at

http://www.campaigntoendaids.org/site/c.fnJMKLNmFmG/b.1067107/k.7325/C2EA_Action_Alert.htm

[Note to Webmasters: please use simpler and more meaningful links when possible. And DO keep putting action alerts on the Web, instead of sending them by email only, r 3]

so that people can more easily write and talk about them, and refer others to the latest version. Change the alert on your Web site when the situation changes; find ways to tell visitors what they can do now.]

People should realize that each billion dollars of medical care denied by Medicaid would cost much more to buy out of pocket. This is because private and public insurance companies make deals to keep prices down, while there is no such restraint on prices for the few who must pay for care themselves. The exact same service can cost you two or three times as much as an insurance company would pay (it is hard to get figures because real prices for U.S. health care are often kept secret or deliberately obscured). The result of this system is nominal prices that do not reflect any economic reality except that you may get trapped and have to pay them.

With Medicaid cuts, of course, poor people will not get the treatment they need. It is well known that tens of thousands of Americans die every year due to lack of health insurance, and the cuts now being made and proposed will cause more to die.

We should also pay more attention to the absurd results of co-pays and other "moral hazard" charges -- intended less to raise revenue than to reduce the use of medical care, supposedly to prevent abuse and therefore save money. But with rare exceptions people do not take medical treatment for fun -- and patients cannot safely second-guess their doctor's recommendations, making their own decisions on which are necessary and which are frills. When co-pays work as intended, they "work" by getting patients to avoid medical care, or to not fill some or all of their prescriptions -- resulting in treatment that could be worse than useless for the individual, while breeding resistant viruses and bacteria for the community.

Probably most patients do not plan and ask the doctor in advance which medicines to stop if they cannot afford them all, so this process has no medical input or

supervision. Doctors often could not make these decisions anyway, as nowhere in drug design, discovery, development, approval, or regulation is treatment modification by arbitrarily dropping some pills due to affordability or co-pays considered.

The real effect of many cost-sharing plans (especially those for the poor) is to ration medical care by social class, not medical need.

Political Mobilization: Not Enough Being Done

Some good work is being done to mobilize for sane policies on access to medical care [2] -- but not enough of it.

Too few organizations are working on the issue. And few have learned how to connect with people effectively, get them involved, and get things done. Washington-based groups are closest to Congress and other machinery of government, but usually speak to policy and other professionals. They often fail to give most people meaningful, coherent images and information they can use, and meaningful ways to act.

Failures of government happen for a reason. Washington is filled with inside games, signposts, symbolisms, score-keeping, etc. that mean nothing to 99% or more of the nation's population. It only takes a few days of working there to start relating to inside cliques and scenes that are meaningless to almost any real constituency. Washington is out of touch because it works within an unreal world -- and with billions of dollars flowing through that world every week, generating enormous influence (about \$1,500,000,000 per week for the Iraq war alone), Washington naturally responds more powerfully to corruption than to voters, information, national interests, values, or anything else.

Trained or experienced organizers know that people are usually best reached through existing groups; they want to act

with their friends, or to meet new friends with shared interests. Issues that work to mobilize action are likely to offer people attractive, coordinated statements about who they are -- practical, effective, intelligent, helpful and loyal to their friends, and supportive of the overall public interest, for example. Supporters must have confidence that the campaigns they are asked to help have been carefully considered.

Leaders of our community need to do better in bringing together experienced organizers, strategy, ideas, media, money, and other elements necessary for success.

References

[1] A "Perfect Storm" Brews, by Bob Adams, *HIV Plus* magazine, October 2005.
http://hivplusmag.com/column.asp?id=686&categoryid=1&issue_emi=current&jt=0

[2] Here is a partial list of HIV-related links on organizing and advocacy for U.S. access to medical care. Let us know of others that should be added.
<http://www.taepusa.org/index.html>
<http://www.campaigntoendaids.org/>
<http://www.tiicann.org/>
<http://www.housingworks.org/>
<http://thebody.com/ryanwhiteaction/>
<http://www.atac-usa.org/default.asp?ID=1>
<http://www.aidsaction.org/>

U.S. Treatment Guidelines: New Version, October 2005

The October 6, 2005 guidelines have relatively few changes, but they are important for some patients.

For those beginning antiretrovirals, the guidelines now say that the combination of an NNRTI + didanosine plus tenofovir should *not* be used, due to virologic failure and development of resistance. And the guidelines do not recommend ritonavir-

boosted tipranavir in treatment-naive patients, due to the lack of clinical-trial data.

For experienced patients, "This section has been updated to redefine the goal of antiretroviral therapy in the management of treatment-experienced patients with virologic failure and to review the role of more potent ritonavir-boosted protease inhibitors such as tipranavir with or without enfuvirtide in these patients."

Much of the guidelines material is presented in a series of tables. The second page, titled "What's New in the Document," also notes the tables that have been changed.

This and other U.S. government guidelines are available at <http://www.aidsinfo.nih.gov/guidelines/>

New California Law: Insurers Cannot Deny Organ Transplants Solely Because of HIV

In late September 2005, California became the first state to prohibit health insurance companies from denying coverage for organ transplantation solely because the patient has HIV. Governor Arnold Schwarzenegger signed the bill, AB 228, which had been passed with bipartisan support in August.

Major health insurers in California and elsewhere have already paid for

transplantation in persons with HIV for the past several years, though some smaller insurers have not made a decision yet. Denials have occurred in some other states, but many have been overturned through appeals.

One-Day HIV Treatment Meeting Near Boston, November 11

Search for a Cure will hold a one-day free meeting on new drugs in the pipeline, HIV treatment strategies, and clinical trials, Friday November 11, 8:30 a.m. to 4:30 p.m. This New England conference, to be held in the Boston area, is intended for both patients and medical professionals. Speakers include Cal Cohen, M.D., Ken Mayer, M.D., Peter Leone, M.D., and Eric Rosenberg, M.D.

Breakfast and lunch will be served. One day of CME/CEU credit will be available.

Location, program, schedule, and other information will be posted on the SFAC Web site, <http://www.searchforacure.org>

HIV Treatment in Resource-Limited Settings: Call for Information

by John S. James

AIDS Treatment News gets email requests for information about treatment options in developing countries around the world -- from patients, family members or friends, and organizations. We need something useful to send to people who know or suspect that they have HIV infection. But little has been written for them. Perhaps our readers could suggest material that has been found helpful, or could help us in writing new fact sheets if necessary.

Of course access to care will vary greatly

in different countries. But many people will want to know about

1) how to find programs that provide treatment (including Global Fund and PEPFAR, MSF, the Red Cross, other private organizations, religious clinics and hospitals, pharmaceutical companies, employers, the national government in some cases, and others) -- what they may offer, and how to find out about or contact them;

2) how well-informed physicians provide care when many of the tests and drugs used in rich countries are not available;

3) what else is involved in HIV care besides antiretrovirals, and the fact that some patients will not need to use those drugs at this time;

4) preventing pneumocystis and some other infections with cotrimoxazole, inexpensive and recommended by the World Health Organization for several years but still not widely used (more evidence favoring it has been published recently);

5) tuberculosis and HIV;

6) special considerations when treating HIV in children;

7) where to find more information, including brief fact sheets for patients and the public, and treatment materials primarily for medical professionals -- and where to find information in different languages;

8) how to prevent transmission to others, and how those who are not infected can protect themselves;

9) ways to help deal with stigma; and

10) what is happening worldwide in treatment access, prevention of new infections, and other means to control the epidemic -- and what needs to happen, and how individuals could join with others to help.

Here are a few of the documents we have found so far:

TAC's Treatment Literacy campaign in South Africa,
<http://www.tac.org.za/> (select "Treatment Literacy" in column on left);

Fact sheets being prepared by the AIDS Alliance in India,
<http://www.aidsalliance.org/sw19588.asp>;

Fact sheets from the New Mexico AIDS Infonet (also available in Spanish, and sometimes in other languages),
<http://www.aidsinfonet.org>;

Extensive training materials for medical professionals through GALEN (Global AIDS Learning and Evaluation Network) and the International Association of Physicians in AIDS Care (IAPAC),
<http://www.iapac.org/home.asp?pid=184>.

Of course the World Health Organization and other international agencies have relevant information, but it is seldom written for patients or their family members or friends. And any group that is providing treatment in resource-limited settings will have information, but it may be hard to find online, as their Web sites are usually written for the general public and other potential funders.

If you have suggestions or recommendations for this project, send them to *AIDS Treatment News*, aidsnews@aidsnews.org (start the subject line with "globaltx" without the quotation marks to help bypass spam control -- although we should get your message in any case).

Got Medicare? What People Living with HIV Need to Know about the New Medicare Drug Benefit - "Part D" - Starting January 1st, 2006

By Suzy Subways

AIDS Treatment News #415, September 30
About one in five people in HIV care has Medicare coverage—and most of those
800-TREAT-1-2

also get Medicaid benefits. For everyone eligible for Medicare, a complicated new program called Part D will help pay for medicines starting January 1, 2006. For Medicare recipients not on Medicaid, the program is optional, but if they choose to enroll after May 15, there will be a penalty of higher premiums. Everyone who gets both Medicaid and Medicare benefits ("dual eligibles") will automatically be enrolled in Part D.

Choosing a Plan

Because the lawmakers who passed it favor free-market capitalism over simplicity, there will be "50 to 100 different plans, all advertising" to consumers, says Tom McCormack, a public benefits policy consultant at Title II Community AIDS National Network (TIICANN). Beneficiaries can select the plan they expect will work best for them. Beginning in late October, extensive information about each plan's formulary, which pharmacies they will cooperate with, and what monthly premiums and co-pays they will charge will appear on www.medicare.gov. Those who do not have access to the Internet can call 1-800-MEDICARE (1-800-633-4227). TTY users can call 1-877-486-2048.

If you are on Medicare and your medications are currently paid for by Medicaid, they will no longer be paid for by Medicaid starting January 1, 2006. Dual eligibles will have a plan randomly chosen for them to make sure that they have Part D in place on time and their treatment is not interrupted. Advocates had worried that many dual eligibles would be too incapacitated by their illness to deal with the paperwork to choose their own plan. Still, those who are able to and want to can

make their own choice. In October, a notice should be mailed explaining the plan chosen for you (if you are on both Medicare and Medicaid), and how you can choose another plan if you prefer. You can join a Medicare Part D drug plan starting November 15, 2005.

Formularies

None of the Part D plans may reject a patient for having an "expensive-to-treat" condition like HIV. And all antiretrovirals must be covered by every plan. However, for most classes of other medications, a plan only has to cover a minimum of two drugs for each condition. For example, there are more than two drugs commonly used to treat PCP pneumonia, but under some of these plans, doctors may need to choose between two that are covered by their patient's Part D plan.

McCormack says it looks like there won't be problems getting newer drugs. "The plans don't appear to be chintzy," he says. But if a drug you need isn't on your plan's formulary, there is a "clunky, hard-to-use appeals process" to get the plan to cover it.

Low Costs for Low-Income Beneficiaries

Part D doesn't pay for medications outright—it requires even the poorest patients to "share" the expenses. Dual eligibles, and those who are eligible for a Medicare Savings Program or get Supplement Security Income (SSI) benefits, automatically qualify for "extra help" to reduce their out-of-pocket costs. For those with an income below the poverty line (currently \$798 per month for a single person, in September 2005), there will be no premiums or deductibles, but there will be a co-pay of \$1 for generic meds and \$3 for brand-name meds, with no co-pay after total drug expenses reach a certain limit. Dual eligibles with incomes between the poverty line and 135% of the poverty line (currently \$1,077 per month for a single person) will have a \$2 co-pay for generics and a \$5 co-pay for brand-